

## REMARKS

Claims 1-3, 8, 11, 12, 14, 15 and 17-28 are pending in the present application.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

Rejections Under 35 USC §103(a) Over Bhat et al. (WO 96/25913) in view of Gavin et al (WO01/00151)

Claims 1-3, 8, 11, 12, 14, 15 and 17-28 remain rejected under 35 USC §103(a) as being unpatentable over Bhat et al. (WO 96/25913) in view of Gavin et al (WO01/00151). Applicants respectfully traverse this rejection.

The Office Action asserts Bhat et al. teaches compositions comprising monophasic zinc hydroxycarbonate as antimicrobial agent in personal care products, such as shampoos, wherein there is a synergistic action of zinc hydroxycarbonate with detergent and/or anti-dandruff actives like zinc pyrithione in shampoos/hair dressings. The Office Action thus asserts that the art has already established compositions comprising zinc hydroxycarbonate and zinc pyrithione in personal care products.

The Office Action further asserts that the difference between the instant application and Bhat et al. is that Bhat et al. do not expressly teach the amount of zinc pyrithione present, the various 'augmentation factors', or gallery ions in the zinc containing layered material. The Office Action asserts that this deficiency in Bhat et al. is cured by the teachings of Gavin et al. The Office Action further asserts that the difference between the instant application and Bhat et al. is that Bhat et al. does not expressly teach a methods for preparing a personal care composition by reacting in a personal care composition comprising zinc pyrithione a carbonate or bicarbonate with a zinc compound, wherein the molar ratio is between about 1:10 and about

10:1; and wherein the zinc pyrithione and the basic zinc carbonate are simultaneously or step wise generated. The Office Action asserts that this deficiency in Bhat et al. is cured by the teachings of Gavin et al. The Office Action further asserts the difference between the instant applications and Bhat et al. is that Bhat et al. do not expressly teach a method of treating microbial or fungal infections. The Office Action asserts that this deficiency is cured by the teachings of Gavin et al. Applicants respectfully traverse these assertions.

The Office Action has raised three objections with regard to the 1.132 Declaration submitted in the previous response dated February 17, 2011. The Office Action asserts that Applicant has not defined what the "impurities" might be. At best, the Office Action asserts that the instant specification states that the idea stoichiometry for zinc carbonate can vary slightly and other impurities may be incorporated in the crystal lattice. The Office Action asserts that water can be interpreted as an impurity and nothing has been argued against that rationale. Applicants traverse this assertion. Water would not provide the impurities demonstrated in the X-ray diffraction data that was previously submitted in the 1.132 Declaration dated May 25, 2010. As defined in this Declaration, as well as known to one of skill in the art, X-ray diffraction is as follows:

--Within the field of x-ray diffraction of **crystal** structures, "monophasic" means that only a single material is identifiable by its x-ray diffraction pattern. For example, a representative article in the field describes the synthesis of a monophasic **solid**  $\text{Ce}_{0.5}\text{Zr}_{0.5}\text{O}_2$  verified by observing only the peaks in the diffraction pattern associated with this material ((J Mater Sci (2207) 42:3557-3563); Page 3560; attached). When different preparative conditions are used, multiple phases are observed to be present in the diffraction spectra (Page 3561).--

Applicants assert that x-ray diffraction, as provided above, requires a crystal structure and thus a solid. Water is not a "solid" structure and would not provide the x-ray diffraction impurities provided by the Declaration of May 25, 2010. Water would need to be in the form of a solid, such as ice, in order to be measured in an x-ray diffraction. Therefore, water cannot be

interpreted an impurity in the present application, as supported by the Declaration of May 25, 2010 as well as the instant specification. The instant specification states that the idealized stoichiometric for basic zinc carbonate is represented by  $Zn_5(OH)_6(CO_3)_2$  but the actual stoichiometric ratios can vary slightly and other impurities may be incorporated in the **crystal lattice**. Therefore, in order for such impurities to be demonstrated in x-ray diffraction, they are in the crystal lattice, and therefore a solid, and not water. Applicants respectfully traverse this assertion and request this rejection is removed.

The Office Action further asserts that impurities suggested by Bhat et al. are directed to other mineral deposits as discussed on page 1, lines 23-33 of Bhat et al. which states zinc hydroxycarbonate occurs in nature as mineral hydrozincite. Bhat et al. states that calcite, dolomite and sometimes quartz occur as materials associated with zinc blend or sulphide. The reference then states that the monophasic zinc hydroxycarbonate prepared by process of Bhat et al. has a structure similar to that of hydrozincite without any other impurity phases as may be present in the mineral. The Office Action asserts that therefore the “impurity phase” of Bhat et al. are those mentioned above such as calcite, dolomite and calamine. The Office Action further asserts that the present claims require an unidentified “impurity” and not an “impurity phase” is contained in the basic zinc carbonate. The Office Action asserts that it is perfectly acceptable that the material of Bhat excludes an impurity phase. Bhat does not exclude water or other ions from their material. Therefore, Examiner maintains that while Bhat describes their monophasic zinc hydroxycarbonate it still contains “impurities”. Applicants respectfully traverse this assertion.

Bhat et al. clearly states that the monophasic zinc hydroxycarbonate prepared by the process of Bhat’s invention has a structure that is similar to that of hydrozincite without any impurity phases as may be present in the mineral. Based on this disclosure, there is no basis for suggesting that an impurity of any kind can be included in the zinc hydroxycarbonate disclosed

in Bhat et al. Therefore, Applicants respectfully traverse the assertion of the office action and request removal of this rejection.

The Office Action asserts that the data present in the 1.132 Declaration submitted February 17, 2011 is directed toward “relative zinc lability”, which is not a claim limitation but rather an “augmentation factor” is claimed and nothing has shown how the samples relate to this “augmentation factor”. Applicants respectfully traverse this assertion. Applicants note that the 1.132 Declaration (February 17, 2011) discloses IMAC Study AD-50 comparing 3 sources of basic carbonate (Bruggemann, Cater, Elementis) and the relative zinc lability and IMAC Efficacy. This 1.132 Declaration demonstrated that there is a significant reduction in Malassezia count for Bruggemann at 251.2 when compared to Cater at 155.7 and Elementis at 214.1. The data indicates a strong correlation between zinc lability and product efficacy, as expected from the mechanistic understanding: “zinc lability” is a measure of the ability of a material to release zinc ions, which are the source of the augmentation benefit. A basic zinc carbonate without any other impurity phases or monophasic, such as those from Elementis and Cater, do not possess the same efficacy as an impurity containing basic zinc carbonate, such as Bruggemann as evidenced by the supporting data in the 1.132 Declaration. As defined in the present invention, an “augmenting factor” is the ratio of the MIC with and with out an augmenting agent i.e. basic zinc carbonate. Augmenting agents, as defined in the present specification, are generally specific to the material being augmented, forming a unique combination and often because there is a special chemical or biological mechanism required to achieve the augmentation effect (page 28, lines 10-13). The supporting data in the 1.132 Declaration demonstrates that for the augmenting agent, basic zinc carbonate, the relative zinc lability is a measure of the ability of the augmenting agent to release zinc ions, which are the source of the augmentation benefit demonstrated in both the data presented in the 1.132 Declaration, as well as the data in the present invention on page 28, lines 14-25. There is no supporting data in Bhat et al. for the augmenting effect of basic zinc carbonate on ZPT for in vivo Malassezia reduction capability. The mere disclosure that, as asserted by the Office Action, wherein since Bhat states that zinc hydroxycarbonate releases zinc ions

acting on the skin flora (page 8, line 13-16) Bhat thereby acknowledges that these compounds have a “relative zinc lability” is incorrect. As support by the 1.132 Declaration (February 17, 2011) there is undue experimentation that has led to the present invention. The assertion by the Office Action which states that essentially it comes down to judicious selection of known sources of zinc hydroxycarbonate is inaccurate. If one of skill in the art were to look to Bhat et al. in view of Gavin et al, they would be led to the monophasic zinc hydroxycarbonate of Bhat et al, which Bhat et al. has stated contains no impurities and Applicants have presented data that shows that monophasic (no impurities) is not as efficacious. The 1.132 Declaration (February 17, 2011) data demonstrates such differences of basic zinc carbonate without impurities (monophasic such as Cater and Elementis) vs. impurity containing basic zinc carbonate (e.g. Bruggemann) are important to the behavior of basic zinc carbonate, as the higher purity materials (closer to monophasic) have lower IMAC Efficacy (Reduction in Malassezia Count), as demonstrated in Table 1 and Graph 1. There is no disclosure in Bhat et al. in view of Gavin et al. that would lead one of skill in the art to even consider *impurity* containing basic zinc carbonate. Bhat et al. in view of Gavin et al. teaches just the opposite. Bhat et al. specifically teaches a process for preparing monophasic zinc hydroxycarbonate. Bhat et al in view of Gavin et al. does not provide any teachings or direction to look to any other source of zinc hydroxycarbonate. And further there is no teaching in Bhat et al. in view of Gavin et al. that would lead one of skill in the art to further find a strong correlation between zinc lability and product efficacy, as expected from the mechanistic understanding: zinc lability is a measure of the ability of a material to release zinc ions, which are the source of the augmentation benefit.

There is no motivation to combine the teaching of Bhat et al. with Gavin et al. and arrive at the claimed invention, as neither Bhat et al. nor Gavin et al. disclose an impurity containing hydroxy-containing basic zinc carbonate. Accordingly, the rejection is untenable and should be withdrawn.

Applicants would like to note the following, as further found in the Office Action at Page 2:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Applicants highlight, for emphasis purposes, that the above patent statute states -- the prior art are such that the subject matter *as a whole* would have been obvious at the time the invention--.

In the prosecution of the present application, Applicants note that in the present office action, the rejections under 35 USC §103(a) is Over Bhat et al. (WO 96/25913) in view of Gavin et al (WO01/00151). In the Office Action mailed on 04/27/2007, Claims 1-4, 8, 9, 11, 12, 14-17 and 23-25 were rejected under 35 USC §103(a) Over Gavin et al (WO01/00151) in view of Bhat et al. (WO 96/25913). Applicant filed subsequent amendments and arguments against the above rejection (Gavin et al (WO01/00151) in view of Bhat et al. (WO 96/25913) on 10/23/07.

In a subsequent office action mailed on 03/04/2009, at page 2, under "Withdrawn rejections" it states that "Applicant's amendments and arguments filed 10/23/07 and 2/14/08 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn. Applicant's amendments and arguments have overcome the rejections of record and those rejections are withdrawn by the Examiner." From this statement, the Applicant's amendments and arguments filed on 10/23/07 which were in response to the above rejection (Gavin et al (WO01/00151) in view of Bhat et al. (WO 96/25913) have overcome this rejection of record and this rejection is withdrawn by the Examiner.

However, in a subsequent Office Action mailed on 11/25/09, Claims 1-3, 8, 11, 12, 14, 15 and 17-28 were rejected under 35 USC §103(a) Over Bhat et al. (WO 96/25913) in view of

Gavin et al (WO01/00151) and this rejection has been maintained in further Office Actions mailed on 5/25/10 and 8/17/10. This new rejection appears misplaced in view of the earlier withdrawal of the claim rejection over identical art.

Applicants re-assert that they have successfully overcome wherein “the prior art are such that the subject matter *as a whole* would have been obvious at the time the invention”. Applicants successfully overcame the 35 USC §103(a) rejection of Gavin et al (WO01/00151) in view of Bhat et al. (WO 96/25913). Therefore, the subject matter of the present invention as a whole is not obvious in view of Gavin et al (WO01/00151) in view of Bhat et al. (WO 96/25913). And the re-ordering of this art rejection, wherein the rejection is USC §103(a) Over Bhat et al. (WO 96/25913) in view of Gavin et al (WO01/00151) is inconsistent. The Office Action asserts that the present rejection of Bhat et al in view of Gavin et al. is different from the prior rejection as the Office Action is relying on different teachings in each respective piece of art and it is not inconsistent to have this current rejection applied and maintained especially when the primary reference of Bhat teaches the desired property of zinc lability in the zinc hydroxycarbonate. However, Applicant maintain that the subject matter of the present invention *as a whole* has been found to be not obvious in view of Gavin et al (WO01/00151) in view of Bhat et al. (WO 96/25913) and once this finding has been established, it is inconsistent to further find that the subject matter of the present invention *as a whole* is now obvious in view of Bhat et al. (WO 96/25913) in view of Gavin et al (WO01/00151). Applicants have overcome the rejection of this prior art and the Office Action of 03/04/09 has withdrawn this rejection. Therefore, the subject matter of the present invention as a whole has been previously found to be not obvious in view of either Gavin et al (WO01/00151) in view of Bhat et al. (WO 96/25913) and such should be considered not obvious in view of Bhat et al. (WO 96/25913) in view of Gavin et al. Applicants respectfully request reconsideration and withdraw of this rejection.

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Conclusion

This response represents an earnest effort to place the application in proper form and to distinguish the invention as now claimed from the applied references. In view of the foregoing, reconsideration of this application, entry of the amendments presented herein, and allowance of Claims 1-3, 8, 11, 12, 14, 15 and 17-28 is requested.

Respectfully submitted,

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